

SEP 20 2004

**ADMINISTRATIVE INFORMATION**

Manufacturer Name: MacroPore Biosurgery, Inc.  
6740 Top Gun Street  
San Diego, CA 92121

Official Contact: Kenneth K. Kleinhenz  
Director of Regulatory Affairs  
Telephone (858) 458-0900  
Fax (858) 458-0994

**DEVICE NAME**

Classification Name: Suction Lipoplasty System  
Trade/Proprietary Name: MacroPore Puricel Lipoplasty System

**ESTABLISHMENT REGISTRATION NUMBER**

2031733

**DEVICE CLASSIFICATION AND PRODUCT CODE**

As shown in 21 CFR 878.5040 Suction Lipoplasty Systems are defined as devices consisting of collection bottles, cannulas, and connecting tubing for use in aesthetic body contouring procedures. Suction Lipoplasty Systems are classified as Class II. They have been assigned Product Code MUU.

)K09226/

**INTENDED USE**

The MacroPore Puricel Lipoplasty System is intended for use in the following surgical specialties when the fragmentation, emulsification, and aspiration of soft tissue is desired:

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery

The MacroPore Puricel Lipoplasty System is indicated for use when the fragmentation, emulsification, and aspiration of subcutaneous fatty tissues for aesthetic body contouring is desired.

**DEVICE DESCRIPTION****Design Characteristics**

The MacroPore Puricel Lipoplasty System is a single use, pre-assembled, manual lipoaspirate system that relies on house vacuum for its energy supply. The MacroPore Puricel Lipoplasty System consists of a cannula, connection tubing, and a waste collection container. The cannula handle is attached to the collection canister via connection tubing. The cannula is a hollow tube with a single opening near the tip to communicate house-vacuum to the tissues and subsequently fragment, emulsify, and aspirate subcutaneous fatty tissues from the patient into the waste collection canister for purposes of aesthetic body contouring. The collection canister contains various capped / sealed ports and a filter to trap large tissue masses

The Puricel Lipoplasty cannula is provided in various sizes ranging from 15cm – 36cm in length and 3.0 – 4.6mm in diameter with a single opening near the tip of the cannula. The tip region of the cannula may have a single or multiple openings that range in size from 4mm to 12mm in length distributed uniformly or randomly throughout the end of the cannula. The handle of the device is 20mm in diameter and may be provided in diameters ranging from 20mm to 60mm in diameter. The connecting tubing is provided with an inner diameter of 9.6mm (3/8”), an outer diameter of 14.3mm (9/16”), and a wall thickness of 2.2mm. The tubing that connects the cannula handle to the waste canister is provided in a length of 4 feet and may be provided in lengths ranging from 1 – 8 feet. The bottom of the waste collection container is also provided with the same 3/8” inner diameter connection tubing of various lengths. The proximal end of the exiting connection tubing may be provided with a barbed tubing connector to assist in the attachment of like-sized tubing for purposes of connecting the MacroPore Puricel Lipoplasty System to house vacuum and / or assorted waste traps. Connection tubing leading to and from the waste collection container is provided with a stepped clamp to allow the operator to seal the connection tubing on both sides of the waste container and prevent spillage of the collected fluids / tissues.

**Material Composition**

The components of the MacroPore Puricel Lipoplasty System that have patient contact are fabricated from surgical stainless steel.

**In Vitro Testing**

Mechanical testing of the MacroPore Puricel Lipoplasty System demonstrates that the device is substantially equivalent to the predicate.

**EQUIVALENCE TO MARKETING PRODUCT**

MacroPore Puricel Lipoplasty System shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: Byron Medical Lipoplasty / Liposuction Aspiration and Tumescent Infusion Cannulae and Needles and Sound Surgical Soundvaser System, Class II medical devices that were cleared for marketing in the United States under K981172 and K022051 respectively.

**Indications For Use**

The MacroPore Puricel Lipoplasty System and the predicate devices share substantially equivalent indications for use as they are all indicated for aspiration of soft tissues in aesthetic body contouring procedures. The MacroPore Puricel Lipoplasty System shares identical indications for use language with the predicate devices.

**Design and Materials**

The design and materials of MacroPore Puricel Lipoplasty System and the predicate devices (Byron Medical Lipoplasty / Liposuction Aspiration and Tumescent Infusion Cannulae and Needles and Sound Surgical Soundvaser System) are substantially equivalent as they are all hollow tubular cannulas attached to a handle. The cannula tip of the subject device and the predicate devices contains one or several openings to allow communication between the applied vacuum and the patients tissues. The MacroPore Puricel Lipoplasty System and the Sound Surgical predicate device are substantially equivalent in design as they both consists of a cannula, connection tubing, and a waste collection container. The waste collection containers on the MacroPore Puricel Lipoplasty System and Sound Surgical predicate device are provided in substantially equivalent volume capacities.



SEP 20 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Kenneth K. Kleinhenz  
Director of Regulatory Affairs  
MacroPore Biosurgery, Inc.  
6740 Top Gun Street  
San Diego, California 92121

Re: K042261  
Trade/Device Name: MacroPore Puricel Lipoplasty System  
Regulation Number: 21 CFR 878.5040  
Regulation Name: Suction lipoplasty system  
Regulatory Class: II  
Product Code: MUU  
Dated: August 20, 2004  
Received: August 24, 2004

Dear Mr. Kleinhenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

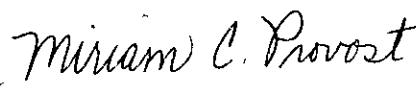
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Kenneth K. Kleinhenz

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Device Name: MacroPore Puricel Lipoplasty System

### Indications for Use:

The MacroPore Puricel Lipoplasty System is intended for use in the following surgical specialties when the fragmentation, emulsification, and aspiration of soft tissue is desired:

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Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

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